

CLAIMS

The invention claimed is:

5 1. A test medium for use with a health monitoring device, comprising:

 a test strip for receiving and carrying a sample of biological fluid or tissue;

 the test strip carrying the sample of biological fluid or tissue being
10 readable by the health monitoring device to obtain test results based on the sample of biological tissue or fluid and calibration data specific to the test strip;

 the test strip corresponding to a memory device readable by the health monitoring device, the memory device storing a code number and the calibration data;

15 the test strip having an associated test strip identification number that is mathematically derivable from the code number;

 the test strip identification number being receivable by the health monitoring device through a user input device; and

 the test strip identification number being usable to activate the health
20 monitoring device for use with the test strip only if the received test strip identification number corresponds to a test strip identification number mathematically derived by the health monitoring device based on the code number read from the memory device.

25 2. The test medium of claim 1, wherein:

 the memory device also stores an expiration date for the test strip;

 the expiration date is readable by the health monitoring device; and

 the expiration date is usable to activate the health monitoring device for
30 use with the test strip only if the expiration date is prior to a current date read by the health monitoring device from an internal clock.

3. The test medium of claim 1, wherein the memory device comprises a romkey insertable into a socket housed within the health monitoring device.

5 4. The test medium of claim 1, wherein:

a plurality of the test strips are packaged for distribution together with the romkey; and

the test strip identification number is printed on the test strips, printed on packaging for the test strips, or printed on a tag packaged with the test strip.

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5. A hand-held health monitoring device, comprising:

an enclosure for housing a disposable test strip for use with the health monitoring device;

15 a holder for removably supporting a device for gathering a sample of biological fluid or tissue;

a test strip reader operable for reading the test strip carrying the sample of biological fluid or tissue and obtaining test results based on the sample of biological tissue or fluid and calibration data specific to the test strip;

20 a memory reading device functionally connected to the test strip reader and operable for reading the calibration data from a memory device;

a user input device operable for receiving user input commands;

a display device operable for displaying information;

25 a processor functionally connected to the test strip reader, the user input device, and the display device, the processor containing a program module operable for obtaining the test results from the test strip reader and causing the display device to display the test results; and

a data drive functionally connected to the processor and operable for writing the test results to a removable memory storage device.

6. The health monitoring device of claim 5, wherein the processor is further operable for:

determining whether a personal identification number has been previously stored on the removable memory storage device;

5 if the personal identification number has not been previously stored on the removable memory storage device prompting the user to enter a personal identification number, storing the received personal identification number on the removable memory storage device; and

10 if the personal identification number has been previously stored on the removable memory storage device, prompting the user to enter a personal identification number, comparing the stored personal identification number to the received personal identification number, and writing the test results to the removable memory storage device only if the stored personal identification number corresponds to the received personal identification number.

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7. The hand-held health monitoring device of claim 5, further comprising:

a clam-shell case openable to reveal first and second compartments;

20 the first compartment containing the enclosure for housing the disposable test strip and the holder for removably supporting the biological fluid or tissue gathering device; and

the second compartment containing the test strip reader, the memory reading device, the display device, the processor, and the data drive.

25 8. The hand-held health monitoring device of claim 5, wherein:
the biological fluid or tissue includes a droplet of human blood; and
the test results include total cholesterol levels.

9. The hand-held health monitoring device of claim 8, wherein the test strip reader is operable for reading a second type of test strip carrying a second sample of biological fluid or tissue and obtaining health-related test results based on the second sample of biological tissue or fluid and calibration

5 data specific to the second type of test strip, further comprising:

a second memory reading device functionally connected to the test strip reader and operable for reading calibration data from a second memory device corresponding to the second type of test strip.

10 10. The hand-held health monitoring device of claim 9, wherein:
the second biological fluid or tissue includes a droplet of human blood;
and
the test results include blood glucose levels.

15 11. A health monitoring device, comprising:

a test strip reader operable for reading the test strip carrying a sample of biological fluid or tissue and obtaining health-related test results based on the sample of biological tissue or fluid and calibration data specific to the test strip;

a memory reading device functionally connected to the test strip reader
20 and operable for reading the calibration data from a memory device;

a user input device operational for receiving user input commands;

a display device operable for displaying information; and

a processor functionally connected to the test strip reader, the user input device, and the display device, the processor containing a diagnostic program
25 module operable for:

obtaining the test results from the test strip reader,

causing the display device to prompt the user to enter diagnostic information using the user input device,

performing a diagnostic analysis to produce diagnostic results
30 based on the test results and the diagnostic information, and

causing the display device to display the diagnostic results.

12. The health monitoring device of claim 11, wherein:
the biological fluid or tissue includes a droplet of human blood;
the test results include blood lipid levels;

5 the diagnostic information includes one or more of the following data items corresponding to a person providing the droplet of human blood:

gender, ethnicity, family history of heart disease, personal history of heart disease, personal history of diabetes, personal history of smoking, height, weight, age, blood pressure, fitness level; and

10 the diagnostic results include one or more of the following data items corresponding to the person providing the droplet of human blood:

a medical risk index, a recommended weight loss, a five-year risk of heart attack, a ten-year risk of heart attack, a cardiac age, an extended age, and a risk of stroke.

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13. The health monitoring device of claim 12, further comprising a data drive functionally connected to the processor and operable for writing the test results, the diagnostic information, and the diagnostic results to a removable memory storage device.

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14. The health monitoring device of claim 13, wherein the processor is further operable for:

determining whether a personal identification number has been previously stored on the removable memory storage device;

5 if the personal identification number has not been previously stored on the removable memory storage device prompting the user to enter a personal identification number, storing the received personal identification number on the removable memory storage device; and

if the personal identification number has been previously stored on the
10 removable memory storage device, prompting the user to enter a personal identification number, comparing the stored personal identification number to the received personal identification number, and writing the test results, the diagnostic information, and the diagnostic results to the removable memory storage device only if the stored personal identification number corresponds to
15 the received personal identification number.

15. The health monitoring device of claim 14, wherein the test strip reader is operable for reading a second type of test strip carrying a second sample of biological fluid or tissue and obtaining health-related test results
20 based on the second sample of biological tissue or fluid and calibration data specific to the second type of test strip, further comprising:

a second memory reading device functionally connected to the test strip reader and operable for reading calibration data from a second memory device corresponding to the second type of test strip.

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16. The health monitoring device of claim 15, wherein:
the second biological fluid or tissue includes a droplet of human blood;
and
the test results include blood glucose levels.

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17. A health monitoring device for use with a disposable test strip, comprising:

a test strip reader operable for reading the test strip carrying a sample of biological fluid or tissue to obtain test results based on the sample of biological

5 tissue or fluid and calibration data specific to the test strip;

a memory device readable by the health monitoring device and storing a code number and the calibration data specific to the test strip;

a user input device operable for entering a test strip identification number into the health monitoring device; and

10 a processor functionally connected to the test strip reader, the memory device, and the user input device, the processor operable for:

reading the code number from the memory device,

mathematically deriving a test strip identification number corresponding to the code number,

15 comparing the received test strip identification number to the derived test strip identification number, and

activating the health monitoring device for use with the test strip only if the received test strip identification number corresponds to the derived test strip identification number.

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18. The health monitoring device of claim 17, wherein:

the health monitoring device also includes a clock defining a current date;

the memory device also stores an expiration date for the test strip;

the processor is operative to read the expiration date and the current date;

25 and

the processor is operative to activate the health monitoring device for use with the test strip only if the expiration date is prior to the current date.

19. The health monitoring device of claim 18, wherein the processor is further operative for:

receiving an activation code through the user input device;

computing an activation code based on the current date and instructions

5 contained in an activation routine stored within the health monitoring device;
and

activating the health monitoring device only if the computed activation code corresponds to the received activation code.

10 20. The health monitoring device of claim 18, wherein the processor is further operable for:

obtaining the test results from the test strip reader,

causing the display device to prompt the user to enter diagnostic information using the user input device,

15 performing a diagnostic analysis to produce diagnostic results based on the test results and the diagnostic information; and

causing the display device to display the diagnostic results.

21. The health monitoring device of claim 20, wherein:
the biological fluid or tissue includes a droplet of human blood;
the test results include blood lipid levels;
the diagnostic information includes one or more of the following data

5 items corresponding to a person providing the droplet of human blood:

gender, ethnicity, family history of heart disease, personal history of heart disease, personal history of diabetes, personal history of smoking, height, weight, age, blood pressure, fitness level; and

the diagnostic results include one or more of the following data items
10 corresponding to the person providing the droplet of human blood:

a medical risk index, a recommended weight loss, a five-year risk of heart attack, a ten-year risk of heart attack, a cardiac age, an extended age, and a risk of stroke.

15 22. The health monitoring device of claim 21, further comprising a data drive functionally connected to the processor and operable for writing the test results, the diagnostic information, and the diagnostic results to a removable memory storage device.

23. The health monitoring device of claim 22, wherein the processor is further operable for:

determining whether a personal identification number has been previously stored on the removable memory storage device;

5 if the personal identification number has not been previously stored on the removable memory storage device prompting the user to enter a personal identification number, storing the received personal identification number on the removable memory storage device; and

10 if the personal identification number has been previously stored on the removable memory storage device, prompting the user to enter a personal identification number, comparing the stored personal identification number to the received personal identification number, and writing the test results, the diagnostic information, and the diagnostic results to the removable memory storage device only if the stored personal identification number corresponds to
15 the received personal identification number.

24. The health monitoring device of claim 23, wherein the test strip reader is operable for reading a second type of test strip carrying a second sample of biological fluid or tissue and obtaining health-related test results
20 based on the second sample of biological tissue or fluid and calibration data specific to the second type of test strip, further comprising:

a second memory reading device functionally connected to the test strip reader and operable for reading calibration data from a second memory device corresponding to the second type of test strip.

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25. The health monitoring device of claim 24, wherein:
the second biological fluid or tissue includes a droplet of human blood;
and
the test results include blood glucose levels.

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26. A system for remotely producing health reports, comprising:
a health monitoring device including:

a test strip reader operable for reading a test strip carrying a
sample of biological fluid or tissue and obtaining test results based on the

5 sample of biological tissue or fluid and calibration data specific to the test strip,
a memory reading device functionally connected to the test strip
reader and operable for reading the calibration data from a memory device,
and

a data drive functionally connected to the test strip reader and
10 operable for writing the test results to a memory storage device;

a health report server operable for:

receiving the test results and additional diagnostic information,

compiling a health report based on the test results and the
additional diagnostic information, and

15 transmitting the health report; and

a computer station operable for:

reading the test results from the memory storage device,

establishing a network connection with the health report server,

receiving the additional diagnostic information,

20 transmitting the test results and the additional diagnostic
information to the health report server,

receiving the health report from the health report server, and

printing the health report.

25 27. The system for remotely producing health reports of claim 26,
wherein the health report includes a trend analysis including test results
compiled for a number of samples of the biological fluid or tissue.

28. The system for remotely producing health reports of claim 26, wherein:

the biological fluid or tissue includes a droplet of human blood;

the test results include blood lipid levels;

5 the additional diagnostic information includes one or more of the following data items corresponding to a person providing the droplet of human blood: gender, ethnicity, family history of heart disease, personal history of heart disease, personal history of diabetes, personal history of smoking, height, weight, age, blood pressure, fitness level.

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29. The system for remotely producing health reports of claim 26, wherein:

the diagnostic results include one or more of the following data items: a medical risk index, a recommended weight loss, a five-year risk of heart attack, 15 a ten-year risk of heart attack, a cardiac age, an extended age, and a risk of stroke.

30. The system for remotely producing health reports of claim 29, wherein:

20 the additional diagnostic information includes a newly-prescribed drug and other currently-prescribed drugs; and

the health report includes a data sheet for the newly-prescribed drug and information relating to cross-reactions between the newly-prescribed drug and the other currently-prescribed drugs.

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31. The system for remotely producing health reports of claim 30, wherein the health report further includes one or more of the following items:

target weight and blood lipid levels;

a schedule for future testing using the health monitoring device.

- 5 a health assessment summary;
a coronary risk assessment; and
dietary guidelines to lower cholesterol.

32. The system for remotely producing health reports of claim 31,
10 wherein the test strip reader is operable for reading a second type of test strip carrying a second sample of biological fluid or tissue and obtaining health-related test results based on the second sample of biological tissue or fluid and calibration data specific to the second type of test strip, further comprising:

- 15 a second memory reading device functionally connected to the test strip reader and operable for reading calibration data from a second memory device corresponding to the second type of test strip.

33. The system for remotely producing health reports of claim 32, wherein:

- 20 the test results include blood glucose levels; and
the health report further includes a trend analysis including test results compiled for a number of sample of the biological fluid or tissue.

34. A secure medical records maintenance system, comprising:

a plurality of removable memory storage devices, each operable for storing medical data for an associated patient, a patient-specified personal identification number, and a medical records identification number secured by

5 the patient-specified personal identification number;

a first remote server operable for storing patient identification information indexed patient identification numbers;

a second remote server operable for storing patient medical data indexed by the medical records identification numbers; and

10 the medical data maintained in the second remote server cannot be correlated to the associated patient identification information maintained in the first remote server based on the information contained in the first and second remote servers.

15 35. The secure medical records maintenance system of claim 34, wherein each removable memory storage device also stores a patient identification number corresponding to the medical records identification number stored on the removable memory storage.

20 36. The secure medical records maintenance system of claim 34, further comprising a correlation table uniquely associating each medical records identification number with a particular one of the patient identification numbers.

37. The secure medical records maintenance system of claim 36, wherein:

the correlation table resides on a practitioner computer associated with a licensed medical practitioner having an assigned professional registration

5 number; and

the first and second remote servers can be accessed by the practitioner computer through encrypted communications secured by an application procedure comprising validation of the practitioner's registration number.

10 38. The secure medical records maintenance system of claim 37, wherein the application procedure further comprises receipt and validation of a client-supplied personal identification number.

39. The secure medical records maintenance system of claim 38, 15 wherein the application procedure comprises issuance of a client certificate insuring that access to the first and second remote servers occurs from the practitioner's computer.

40. The secure medical records maintenance system of claim 34, 20 wherein access is granted to the first remote server, but not to the second server, for the purpose of generating a mailing list of patients without divulging any medical data associated with the patients.

41. The secure medical records maintenance system of claim 34, 25 wherein access is granted to the second remote server, but not to the first server, for the purpose of conducting investigative analyses involving patient medical data without divulging any patient identification information associated with the patients.

42. The secure medical records maintenance system of claim 34, wherein the medical data stored on each removable memory storage device is automatically erased from the memory storage device after the data is entered into the second remote server.

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43. The secure medical records maintenance system of claim 34, wherein the removable memory storage device is receivable within a hand-held health monitoring device operable for storing the medical data on the removable memory storage device.

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44. The secure medical records maintenance system of claim 34, wherein the removable memory storage device is receivable within a computer operable for transmitting the medical data to the second remote server over the Internet.

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45. A health monitoring device operable for:
obtaining medical data associated with a patient;
reading an initial monetary balance stored on a removable memory
storage device;

5 determining whether the initial monetary balance is sufficient to pay a
monetary value assigned to performance of a test involving the medical data to
be performed by the testing device; and
if the initial monetary balance is sufficient to pay for the test,
 computing a revised monetary balance by deducting the monetary
10 value assigned to performance of the test from the initial monetary balance,
 replacing the initial monetary balance with the revised monetary
balance on the removable memory storage device, and
 activating the health monitoring device for performance of the test.

15 46. The health monitoring device of claim 45, further operable for
reading the monetary value assigned to performance of the test from the
removable memory storage device.

20 47. The health monitoring device of claim 45, further operable for
prompting a user of the health monitoring device to replenish the monetary
value stored on the removable memory storage device if the initial monetary
balance is in sufficient to pay the monetary value assigned to performance of
the test.

48. A system operable for performing diagnostic health tests, comprising:

a removable memory storage device;

~~an network-based server operable for remotely charging a cost to a~~

5 payment source and crediting the cost to an initial balance stored on the removable memory storage device; and

a health monitoring device, operable for:

obtaining medical data associated with a patient;

10 reading an initial monetary balance stored on a removable memory storage device;

determining whether the initial monetary balance is sufficient to pay a monetary value assigned to performance of a test involving the medical data to be performed by the testing device; and

if the initial monetary balance is sufficient to pay for the test,

15 computing a revised monetary balance by deducting the monetary value assigned to performance of the test from the initial monetary balance,

replacing the initial monetary balance with the revised monetary balance on the removable memory storage device, and

20 activating the health monitoring device for performance of the test.

49. The system of claim 48, wherein:

25 network-based server operable for remotely storing the monetary value assigned to performance of the test on the removable memory storage device; and

the health monitoring device is further operable for reading the monetary value assigned to performance of the test from the removable memory storage device.

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